

Remarks

Claims

Rejection under 35 USC § 112, first paragraph - enablement:

The Examiner has rejected Claims 53 and 57 as failing to meet the enablement requirement of 35 USC § 112, first paragraph. The Examiner's concerns in summary are stated:

"It is unclear whether this biological material is known and readily available to the public ...".

In response, the Applicant's Agent respectfully draws the Examiner's attention to Attachment A. Page 1 of Attachment A are printed from EMD Biosciences website and list the T7 host strains that are specifically referenced in the rejected Claims 53 and 57 [BL21(DE3), B834(DE3) and HMS 174(DE3)] as well as simple "derivatives" of them (e.g., B834(DE3)pLysS) and more complex "derivatives" [e.g., Origami™(DE3), Rosetta™(DE3), Tuner™(DE3) and their derivatives]. The properties of the various T7 expression strains are more fully described in the EMD Biosciences brochure, entitled "Novagen® Competent Cells", which is attached hereto as Attachment B.

In further support that such cells are readily available to the public, and that the public may seek such expression cells from other suppliers, page 2 of Attachment A is a listing of expression strains from Invitrogen [BL21(DE3) and the Star™ and pLysS and pLysE derivatives of them). Pages 3 – 5 of Attachment A are from Stratagene's website and note the properties of the BL21-CodonPlus® and BL21-Gold (DE3) strains. Pages 6 to 8 of Attachment A are from New

England Biolabs' website. The BL21(DE3) expression strain derivatives that have been developed by New England Biolabs (NEB) offer an alternative to the using T7 expression host cells that harbor the (DE3) lysogen. Each of the T7 expression strains that are offered by NEB have been re-engineered so that the T7 RNA polymerase is stably included in the chromosome, but the λ lysogen sequences have been eliminated.

In addition to the suppliers mentioned above, there are a number of additional commercial entities that have T7 expression cells available for purchase by the public.

The Agent for the Applicant has searched the American Type Culture Collection and notes that the strains specifically referenced in Claims 53 and 57 were not cataloged therein. However, BL21(lambda DE3) (which is a "long hand" designation for BL21(DE3)) is available from the collection of the Institute Pasteur (page 9 of Attachment A). It is likely that the strain is also available from other sources.

The Agent for the Applicant respectfully submits that the evidence included in Attachment A shows that the strains referred to in the rejected Claims 53 and 57 are readily available. Should the availability from commercial entities as noted herein be found insufficient to convince the Examiner to remove this basis for rejection, the Applicant will certainly take the proper steps to ensure that the strains are available from a strain collection such as the American Type Tissue Collection.

Rejection under 35 USC § 112, second paragraph:

Claims 54 – 60 are rejected under 35 USC §112, second paragraph as being indefinite. Claims 54 -56 and 58 -60 have been specifically rejected for referencing “T7 expression system host cells”. Claim 57 has been rejected in addition for the inclusion of “derivatives thereof”.

In response to the rejection based upon the suggested indefiniteness of “T7 expression system host cells”, the base Claim 54 has been herein amended to specifically point out and distinctly claim the subject matter included in “T7 expression system host cells”, i.e., strains containing “an expressible T7 RNA polymerase under the control of a *lac* promoter”.

With respect to the rejection of Claim 57 for recitation of “and derivatives thereof”, the Agent for the Applicant respectfully submits the following remarks. First, as the amendment of Claim 54 notes that a T7 expression system host cell has an expressible T7 RNA polymerase, and therefore, any derivative thereof must also have the expressible T7 RNA polymerase. Second, “derivatives thereof” would be understood by persons of ordinary skill in the art, for example, to mean derivatives such as the Origami and Rosetta strains as the described in Attachment B, page 5 and the Tuner strain as on page 3 of Attachment B from EMD Biosciences, which strains were derived as “improvements” of the BL21(DE3) parental strains. In addition, persons of skill in the art would look to the “CodonPlus®” strains of Stratagene, for example, or the strains of New England Biolabs which do not contain the sequences associated with the lysogen which was used to prepare the parental BL21(DE3) strains. Each of these “derivative”

contain an expressible T7 RNA polymerase and those of skill in the art are readily capable of selecting one derivative or another.

Provisional rejection on the grounds of nonstatutory obviousness-type double patenting:

The Examiner has provisionally rejected Claims 53 – 60 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 40 of copending Application No. 11/704,048, in view of Studier et al. (1986) and Studier et al. (1990).

The Examiner has issued the same provisional rejection over claim 28 of the copending Application No. 11/704,048, in view of Studier et al. (1986) and Studier et al. (1990).

In response, the Agent for the Applicant respectfully notes that the referenced application, as filed, has no claim 40 and, the preliminary amendment entered for the referenced application does not add any claim numbered 40. Based upon the Examiner's remarks of pages 5 – 7, the Applicant's Agent has interpreted the provisional rejection to refer to Claims 1 and 28 of the referenced Application.

In further response and in an effort to advance the present case to a condition for allowance, the Agent notes that the referenced Application No. 11/704,048 derives its priority from the case presently under examination. The Agent further notes that the two applications have the same named inventor who was (and remains) under the obligation of assignment to the common owner of the two applications. Therefore, should the

referenced Claims issue in the present application and the claims of the referenced Application No. 11/704,048 be allowable, the Agent shall, upon the issuance of such a requirement by the Office, enter a terminal disclaimer in the second-to-be-allowed case.

The amendment of Claim 54, herein, having been made in an effort to advance the present case, contains no new matter.

In closing, the Applicant submits that the present application is now in condition for allowance and respectfully anticipates receipt of a timely Notice of Allowance.

Respectfully Submitted,



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